New Project Checklist

Date: _____
Project Title: _____

Protocol ID: _____
Institutional Affiliation: _____
Principal Investigator: _____

I. Type of Review Requested: (*Check only one*)

(See Instructions for Researchers for description of each type of project: http://www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf)

☐ Information Practices Act – Expedited Review
☐ Death Data Only –Expedited Review
☐ Common Rule (***If Common Rule, also choose the type of Common Rule below***)
  ☐ a. Full Committee review for projects with human subject contact
  ☐ b. Expedited Review for data-only projects

Will there be human subject involvement during any phase of this protocol? ☐ **Yes** ☐ **No**

If at any point a protocol is amended to involve human subject contact, research staff must notify CPHS staff immediately via phone or email

II. Personnel Information: (*All project types*)

☐ The Responsible Official is above the PI in the organization's line of authority

III. Vulnerable Populations Checklist: (*Common Rule projects only*)

☐ Minors Checklist attached
☐ Pregnant Women and Fetuses Checklist attached
☐ Neonates Checklist attached
☐ Prisoners Checklist attached (*all projects*)
☐ Not Applicable

IV. Study Location: (*Common Rule projects only*)

☐ All study locations listed
☐ Not Applicable

V. General Checklist: (*All project types*)

In the "Project Type", is either Common Rule, Information Practices Act, or Death Data-Only checked? ☐ Yes ☐ No

VI. Funding: (*All project types*)

Is either "None" or "Funding Source" checked? ☐ Yes ☐ No

If Funding Source is checked, are the sources and amounts included? ☐ Yes ☐ No

VII. Protocol Information:

Are "Start Date" and "End Date" listed? ☐ Yes ☐ No

1. Purpose of the Study: **(*All project types*)**
   Is the purpose of the study clearly stated? ☐ Yes ☐ No

2. Study Procedures: ***All project types*)**
   Are the study procedures clearly stated? ☐ Yes ☐ No

3. Testing of a New Drug or Device ***(Common Rule projects only)***
   If a new drug or device is being tested, are copies of the state and federal documents that permit the investigators to proceed attached? ☐ Yes ☐ No ☐ N/A

4. Study Affiliation: **(*All project types*)**
   a. Is the name of the database or specimens, such as blood spots, listed? ☐ Yes ☐ No ☐ N/A

   b. Is California Health and Human Services Agency staff, funding or state mental hospital patients identified? ☐ Yes ☐ No ☐ N/A

   Note: if neither of these categories are listed, the project may not be in CPHS' purview.

5. Subject Population: **(*All project types*)**
   Is the subject population adequately described? This includes data elements being used, recruitment and screening methods, age, gender, ethnicity, vulnerable populations, and rationale for studying these populations. ☐ Yes ☐ No

6. Risks: **(*All project types*)**
   Are the risks and risk level, minimal or greater than minimal risk, described and justified? ☐ Yes ☐ No

7. Benefits: **(*All project types*)**
   Are the benefits adequately described? It should not include compensation. ☐ Yes ☐ No

VIII. Data Security Requirements

8. Administrative Safeguards**: (*All project types*)**

   a. Are administrative safeguards for data security being met or is there justification for not meeting specific safeguards or providing an alternative safeguard? ☐ Yes ☐ No

   b. Has the individual(s) responsible for the security of this research data submitted a letter or statement that the organization is meeting the CPHS data requirements? ☐ Yes ☐ No

9. Physical Safeguards: **(*All project types)***
   Are the physical safeguards for data security being met or is there justification for not meeting specific safeguards or providing an alternative safeguard? ☐ Yes ☐ No ☐ N/A

10. Electronic Safeguards: ***(All project types)***
    Are the electronic safeguards for data security being met or is there justification for not meeting specific safeguards or providing an alternative safeguard? ☐ Yes ☐ No ☐ N/A

11. Conflict of Interest: ***(All project types)***
    Are there any financial or other relationships of the researcher or institution that could be perceived as as a conflict of interest described? ☐ Yes ☐ No ☐ N/A

12. Informed Consent: **(*Common Rule projects only*)**
    Is a description of the consent procedure included or a waiver consent requested? ☐ Yes ☐ No ☐ N/A

13. Assent Background**: (*Common Rule projects only*)**
    Is a description of the informed assent procedure (for individuals age 7 to 17) included or a waiver of assent requested? ☐ Yes ☐ No ☐ N/A

14. Health Insurance Portability and Accountability Act:
    (*Common Rule and Information Practices Act projects only*)
    If the data being requested is covered by HIPAA, is there a HIPAA Authorization, HIPAA waiver request or the approval of another IRB attached? ☐ Yes ☐ No ☐ N/A

15. Assurance of Consistency between Grant Application

and CPHS Protocol: **(*Common Rule projects only*)**

a. If the project is funded by a grant, is the grant summary that addresses the questions in this section attached? ☐ Yes ☐ No ☐ N/A

b. Are the page numbers or sections of the grant and protocol included? ☐ Yes ☐ No ☐ N/A

16. Attachments: **(*All project types)***

Required Documents: **(*All project types*)**
☐ New Project Checklist
☐ CV or resume of Principal Investigator (PI) and Co-PI
☐ Data Security Letter from staff of the organization who is responsible for the security of the research data
☐ Budget
☐ Cover Letter

Other Possible Items: **(*Please check all that apply*)**
☐ Checklist for Research Involving Minors
☐ Checklist for Research Involving Pregnant Women and Fetuses
☐ Checklist for Neonates
☐ Checklist for Research Involving Prisoners
☐ Informed Consent Form (attach in section 12)
☐ Informed Assent Form (attach in section 13)
☐ Grant application
☐ CV for translator
☐ Surveys and questionnaires
☐ Recruitment material
☐ Other (Please specify): _____

IX. Translations: (*Common Rule projects only*)

Are there or will there be any translations? ☐ Yes ☐ No
Specify the language(s) _____ ☐ N/A

X. Obligations: (*All project types)*

Have the PI and Responsible Official checked this section? ☐ Yes ☐ No